

REMARKS

Entry of the above amendments and consideration of the following remarks are respectfully requested. Upon entry of the above amendments, this application will contain claims 1-28 pending and under consideration. It is submitted that no new subject matter is introduced by these amendments. As more fully discussed below, it is believed that the claims are patentable. Consequently, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §101 and passage of this application to allowance.

Claims 1-15 stand rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-15 of prior U.S. Patent No. 5,989,289. Applicants respectfully disagree with the Examiner's assertions.

The present application claims priority to the cited reference, U.S. Serial No. 08/948,135 ("the '135 application"), now U.S. Patent No. 5,989,289. The present application contains claims 1-15 as originally filed in the '135 application. During prosecution of the '135 application, independent claims 1 and 15 were rejected under 35 U.S.C. §103 over Niwa et al. (U.S. 4,689,919) and Gilles (FR 2 703 580). In response, Applicants amended claims 1 and 15 to recite that the migration resistance grooves include first and second opposing faces, said first and second opposing faces "defining a substantially arcuate pocket". (Additions to the claims are underlined.) The rejections of claim 1 and 15 over the Niwa et al. and Gilles were then withdrawn. These claims eventually issued in U.S. patent 5,989,289. The present claims do not recite that the first and second faces define a substantially arcuate pocket. Consequently, Applicants content that present claims 1-15 cannot claim the same invention as that claimed in U.S. Patent 5,989,289.

The present claims are patentably distinct over Niwa et al. and Gilles either considered singly or in combination. As a starting point the entire invention must be considered as a whole. Applicants claimed invention is directed to a spacer or a graft formed of bone. Bone is selected because this natural material provides distinct advantages as discussed in the application. (Application, page 11, line 12-page 12, line

9.) Bone promotes spinal fusion, provides temporary support, and allows bone ingrowth all the while minimizing stress shielding of the bone ingrowth. Bone is radiopaque. The position and condition of the spacer/graft in the body can be evaluation using common X-ray techniques. Furthermore, the body readily absorbs a bone graft or spacer after spinal fusion when the spacer or graft is no longer needed or desired. The bone spacer or graft can be formed by shaping and machining a bone slice cut from a long bone. Neither Niwa et al. nor Gilles disclose a spinal spacer or graft formed of bone.

Niwa et al. discloses an artificial knee joint. The only materials disclosed for the artificial joint are ceramics. Ceramics are preferred because they provide a joint that exhibits improved strength and durability. (Niwa et al. col. 7, line 65-col. 8, line 9.) The ceramic joint is intended to be strong and permanent. Niwa et al. does not teach or suggest to one skilled to make and use an absorbable bone spacer or graft to promote spinal fusion. Niwa's artificial joint is not designed nor intended to be absorbed by the body. If it were absorbed, the adjacent bone structures would separate. Obviously this is directly contrary to the intended use of the artificial joint. Neither is the joint provided to promote fusion of the adjacent bone structures because to do so would lock the joint and defeat the purpose of the artificial joint. Obviously one could not propose modifying Niwa et al. to arrive at the claimed invention because this would render this Niwa's artificial joint unsatisfactory for its intended purposes.

Applicants have obtained an English translation of Gilles. Gilles discloses an intersomatic housing that is formed of polyethylene. (Gilles, English translation, Abstract and page 4, lines 15-17 and page 5, lines 5-8.) No other materials are disclosed, suggested or taught by this reference. There is no teaching or suggestion that a polyethylene housing can provide the same or similar advantages of the claimed bone spacer or graft as above discussed. For example, the Gilles house must be fitted with a radiopaque marker to follow the displacement of the implant over time. (Gilles, English translation, page 4, lines 26-29 and page 6, lines 17-20.) Bone grafts do not need radiopaque markers.

The claimed graft is also distinguishable because it includes a convexly curved anterior wall surface. The convexly curved anterior wall surface can match the curved

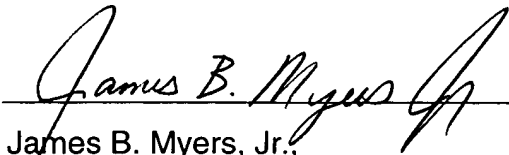
anterior portions of the vertebral bodies and consequently enhance the "fit" of the spacer in a vertebral space and reduce the tendency of the spacer to migrate once implanted inside the vertebral space. The curved surface also minimizes the potential of damage to the tissue surrounding the spacer or graft. Gilles describes and illustrates the housing as having the shape of a parallelepiped. (Gilles, English translation, Figure 1, and page 4.) Neither the bone material nor the curved wall surface are disclosed or suggested by Gilles.

The combined teachings of these references, when considered as a whole, do not make the claimed invention obvious. Neither reference discloses or suggests to one skilled in the art a spacer or graft formed of a bone material as claimed. Neither reference discloses a spacer or graft comprising a cortical bone slice. And neither reference discloses a spacer or graft having a wall between the bone engaging surfaces that includes curved surfaces.

In view of the foregoing discussion, reconsideration, withdrawal of the rejections under 35 U.S.C. §101, and allowance of this application containing claims 1-27 are requested. Additionally, if the Examiner is invited to telephone the undersigned attorney if there are any questions about this submission or other formal matters that can be addressed in that fashion to facilitate allowance of this application.

Respectfully submitted,

By



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